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BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER	
VU, JAKE MINH	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/029,408
Filing Date: December 26, 2001
Appellant(s): CALDWELL ET AL.

Shinae Kim-Helms
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 09/30/2008 appealing from the Office action mailed 02/26/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,709,855	BOCKOW	01-1998
5,989,559	EDWARDS	11-1999

5,869,087	HIRANO	02-1999
2002/0176886	SHUDO	11-2002
WO 02/22109	LIEBSCHUTZ	03-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-3, 5-8, 10-12, 14-18, 29, 34-36, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559).

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel.

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

As one of ordinary skill in the art would be aware of the symptoms of carpal tunnel syndrome, it would be reasonable to expect that successful treatment of this condition would include the amelioration of symptoms such as tingling, numbness, and pain. Therefore, such limitation drawn to the amelioration of such symptoms is considered to be implicitly met by the teachings of the prior art. Additionally, it is expected that successful treatment of carpal tunnel syndrome would conclude with

cessation of such symptoms for an extended period of time, particularly as the claims are drawn to methods of treatment that are open in scope and may therefore include other methods of treatment beyond those that are explicitly recited. Therefore, such claim limitations drawn to the length of the amelioration of such symptoms are also implicitly met by the prior art. Thus, the instantly claimed invention is *prima facie* obvious.

Claims 4, 9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Hirano *et al*. (U.S. Patent No. 5,869,087)

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel, nor does it disclose the topical formulation in the form of a patch

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

The Hirano *et al*. patent is used here to show that it is known in the art that anti-inflammatory drugs such as diclofenac, indomethacin, ibuprofen and ketoprofen may be formulated into a patch, to be included in amounts ranging from 0.1% to 10% by weight (See Column 3, Line 65 to Column 4, Line 19; and Claims 1 and 10).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

One of ordinary skill in the art would be motivated to combine the Bockow patent with the Hirano *et al*. patent in order to treat pain using a topical formulation in the form

of a patch, for the reason that a patch may be considered less messy than the use of a cream or gel. As the Bockow and the Hirano *et al*. patents both deal with topical compositions containing commonly known anti-inflammatory substances, they are considered to be analogous, and therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together.

The examiner finds no novelty claim limitations dealing with the specific placement of NSAID formulations on a subject and shifts the burden onto the Appellant to demonstrate how the instantly claimed invention shows unexpected results from what is known in the prior art. It is the position of the examiner that topical forms disclosed in the prior art such as films sufficiently read on the instantly claimed invention so as to make the use of patches in treatment obvious to one of ordinary skill in the art. Thus, the instantly claimed invention is *prima facie* obvious.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Shudo *et al*. (U.S. Patent Application Publication No. 2002/0176886).

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for

application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel. The Bockow patent does not provide for kits containing a topical formulation and instructions for use according to a claimed method of treatment.

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

The Shudo *et al*. reference discloses kits comprising topical patch formulations as well as instructions for use, which may be printed or embodied in the form of electronic media (See Section 0044).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a

reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

One of ordinary skill in the art would have been motivated to combine the Shudo *et al*. with the aforementioned references, in order to provide topical dosage forms in a kit that further comprises instructions for use in accordance with the treatment of conditions such as carpal tunnel syndrome. As the prior art references disclose the use of topical formulations, they are considered to be analogous such that one of ordinary skill in the art would have a reasonable expectation of success in combining the references together. Thus, the instantly claimed invention is *prima facie* obvious.

Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559), Hirano *et al*. (U.S. Patent No. 5,869,087), and a bandage.

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage

may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel, nor does it disclose the topical formulation in the form of a patch

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

The Hirano *et al*. patent is used here to show that it is known in the art that anti-inflammatory drugs such as diclofenac, indomethacin, ibuprofen and ketoprofen may be formulated into a patch, to be included in amounts ranging from 0.1% to 10% by weight (See Column 3, Line 65 to Column 4, Line 19; and Claims 1 and 10).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

One of ordinary skill in the art would be motivated to combine the Bockow patent with the Hirano *et al*. patent in order to treat pain using a topical formulation in the form of a patch, for the reason that a patch may be considered less messy than the use of a cream or gel. As the Bockow and the Hirano *et al*. patents both deal with topical compositions containing commonly known anti-inflammatory substances, they are considered to be analogous, and therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together.

One of ordinary skill in the art would find it advantageous to use a patch containing an anti-inflammatory drug in conjunction with a bandage. Bandages are well known for holding dressings and other topical formulations in place so as to avoid the loss of contact between the formulation between such a therapeutic composition and the affected area. Bandages are also useful in restricting the movement of a joint afflicted with pain so that the decrease in movement also decreases the chance of a sharp jerk or movement in the joint that may trigger additional pain. In either application, a bandage applied to a subject suffering from carpal tunnel syndrome would constitute a "wrist strap" in the broad sense of the term, without any further or more specific definition by the instant disclosure. Thus, the instantly claimed invention is *prima facie* obvious.

Claims 30-33, 37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Liebschutz (PCT Publication WO 02/22109 A2).

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel, nor does it disclose the use of diclofenac epolamine in an amount of 1.3% by weight in the form of a patch.

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

The Liebschutz *et al*. reference discloses a patch containing diclofenac (See Abstract). The diclofenac may be present in the form of diclofenac epolamine in an amount that is preferably from 1% to 5% of the matrix layer (See Page 3, Section (b)(1)).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

It would be obvious to one of ordinary skill in the art to combine the Bockow patent with the Liebschutz *et al*. reference, as one would be motivated to use the patch disclosed in Liebschutz *et al*. for its disclosed advantages of good adhesion without irritation and improved bioavailability (See Page 2, first paragraph). As the Bockow and Liebschutz *et al*. reference are both drawn to topical formulations of anti-inflammatory drugs such as diclofenac for the treatment of pain, the references are analogous and therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together. Thus, the instantly claimed invention is *prima facie* obvious.

(10) Response to Argument

I. Claims 1-3, 5-8, 10-12, 14-18, 29, 34-36, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559).

Group I:

Appellant argues that the Examiner's rational to combine the prior art references is based on incorrect assumption that Carpal Tunnel Syndrome (herein after "CTS") is a musculoskeletal disorder. First, CTS is not only a well-known neuropathy but also one of the most common neuropathies. Second, CTS and musculoskeletal disorders have entirely distinct pathologies. Third, because these two conditions arise from entirely distinct pathologies, those of ordinary skill in the art generally treat CTS and musculoskeletal disorders differently. Therefore, one of ordinary skill in the art would not read BOCKOW as teaching anything with respect to CTS. The Examiner finds this argument unpersuasive, because BOCKOW explicitly disclosed treating CTS (see col. 6, line 61-62); thus one skilled in the art would have read BOCKOW as teaching a method for treating CTS.

Appellant argues that the Examiner's asserted reason to combine BOCKOW with EDWARDS is based on BOCKOW's incorrect characterization of CTS; therefore, one of ordinary skill in the art would actually not combine the two references to use BOCKOW's formulation in EDWARD's method. The Examiner finds this argument unpersuasive, because others of ordinary skill in the art have characterized CTS as musculoskeletal disorders, such as PETRUS (US 6,399,093 at col. 1, line 5-45), which

is of record in the office action filed on 02/27/2007. Thus, one of ordinary skill in the art would actually combine the two references to use BOCKOW's formulation in EDWARD's method.

Appellant argues that one of skill in the art would not have predicted success in the claimed methods - in particular, the effective delivery of an NSAID formulation to the median nerve inside the carpal tunnel and the subsequent treatment of CTS by the NSAID formulation. First, one of ordinary skill in the art would not have predicted success in the effective delivery of an NSAID formulation to the median nerve inside the carpal tunnel upon topical application to palmar dermis. Second, one of ordinary skill in the would not have predicted success in treating CTS with an NSAID formulation upon reading BOCKOW. The Examiner finds this argument unpersuasive, because BOCKOW explicitly disclosed treating CTS (see col. 6, line 61-62); thus one skilled in the art would have a reasonable expectation of success.

Group II:

Appellant argues that the claim of Group II is not obvious over BOCKOW in view of EDWARDS for the reasons detailed above. The Examiner finds this argument unpersuasive, for the reasons detailed above.

Appellant argues that BOCKOW in view of EDWARDS teach 3% - 25% of an NSAID, but fails to teach a narrower range of NSAID in an amount ranging from about 0.1 to about 5% for treating CTS. The Examiner finds this argument unpersuasive, because the amount of a specific ingredient in a composition is clearly a result effective

parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as decreasing pain. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Appellant's invention.

Group III:

Appellant argues that the claim of Group III is not obvious over BOCKOW in view of EDWARDS for the reasons detailed above for claims of Group I. The Examiner finds this argument unpersuasive, for the reasons detailed above for claims of Group I.

Appellant argues that there is no mention for the use of the composition for the treatment of neuropathic symptoms associated with a carpal tunnel syndrome (note, Appellant's instant claim recites “carpal tunnel syndrome”, not "neuropathy condition", please see claim 34). The Examiner finds this argument unpersuasive, because dependent claim 35 recites the neuropathic symptom as pain. BOCKOW teaches treating symptoms such as pain (see col. 2, line 43); thus, BOCKOW disclosed the use of the composition for the treatment of neuropathic symptoms, such as pain.

Additionally, although BOCKOW is silent about the explicit term “neuropathic symptoms associated carpal tunnel syndrome”, it does not appear that the claim

language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories,* 58 USPQ2d 1508 (CAFC 2001). "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that Appellant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method. Thus, BOCKOW teaches, either expressly or inherently, each and every limitation of the instant claims.

Group IV:

Although BOCKOW is silent about the explicit term "tingling" and "numbness" (note, BOCKOW does explicitly teach the term "pain"), it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories,* 58 USPQ2d 1508 (CAFC 2001). "It is a general rule that merely

discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that Appellant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method. Thus, BOCKOW teaches, either expressly or inherently, each and every limitation of the instant claims.

Group V:

Although BOCKOW is silent about ameliorated for a period of 1 week or londer following application of the topical NSAID formulation, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories,* 58 USPQ2d 1508 (CAFC 2001). "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the

public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that Appellant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method. Thus, BOCKOW teaches, either expressly or inherently, each and every limitation of the instant claims.

Group VI:

Although BOCKOW is silent about amelioration lasts for a period of several weeks or longer, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories,* 58 USPQ2d 1508 (CAFC 2001). "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. On this record, it is reasonable to conclude that the same patient is being administered the same active

agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that Appellant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method. Thus, BOCKOW teaches, either expressly or inherently, each and every limitation of the instant claims.

II. Claims 4, 9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Hirano *et al*. (U.S. Patent No. 5,869,087)

Appellant argues that Claims 4, 9 and 13 are not obvious over BOCKOW in view of EDWARDS because 1) there is no apparent reason to combine teachings of BOCKOW and EDWARDS as asserted by the Examiner based on the background knowledge in the art; and 2) one of skill in the art could not have predicted success in practicing the claimed invention by combining the elements of the prior art references in the manner that they would perform the same function as they did separately, as detailed above for the claims of Group I. As HIRANO was cited solely for the patch element, HIRANO fails to make up this deficiency in the primary references and this rejection may be reversed. The Examiner finds this argument unpersuasive, because of the reasons detailed above for the claims of Group I. Thus, HIRANO does not have to make up this deficiency in the primary references and the rejection should be maintained.

III. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Shudo *et al*. (U.S. Patent Application Publication No. 2002/0176886).

Appellant argues that Claim 19 is not obvious over Bockow in view of Edwards because 1) there is no apparent reason to combine teachings of Bockow and Edwards as asserted by the Examiner based on the background knowledge in the art; and 2) one of skill in the art could not have predicted success in practicing the claimed invention by combining the elements of the prior art references in the manner that they would perform the same function as they did separately, as detailed above for the claims of Group I. As Shudo was cited solely for the kit element, Shudo fails to make up this deficiency in the primary references and this rejection may be reversed. The Examiner finds this argument unpersuasive, because of the reasons detailed above for the claims of Group I. Thus, SHUDO does not have to make up this deficiency in the primary references and the rejection should be maintained.

IV. Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559), Hirano *et al*. (U.S. Patent No. 5,869,087), and a bandage.

Appellant argues that Claims 24-28 are not obvious over BOCKOW in view of EDWARDS because 1) there is no apparent reason to combine teachings of BOCKOW and EDWARDS as asserted by the Examiner based on the background knowledge in the art; and 2) one of skill in the art could not have predicted success in practicing the claimed invention by combining the elements of the prior art references in the manner that they would perform the same function as they did separately, as detailed above for the claims of Group I. As HIRANO was cited solely for the patch element, HIRANO fails to make up this deficiency in the primary references and this rejection may be reversed. The Examiner finds this argument unpersuasive, because of the reasons detailed above for the claims of Group I. Thus, HIRANO does not have to make up this deficiency in the primary references and the rejection should be maintained.

V. Claims 30-33, 37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Liebschutz (PCT Publication WO 02/22109 A2).

Group VII:

Appellant argues that Claims 30 and 31 are not obvious over BOCKOW in view of EDWARDS because 1) there is no apparent reason to combine teachings of BOCKOW and EDWARDS as asserted by the Examiner based on the background knowledge in the art; and 2) one of skill in the art could not have predicted success in practicing the claimed invention by combining the elements of the prior art references in

the manner that they would perform the same function as they did separately, as detailed above for the claims of Group I. As LIEBSCHUTZ was cited solely for the use of diclofenac epolamine in the form of a patch, LIEBSCHUTZ fails to make up this deficiency in the primary references and this rejection may be reversed. The Examiner finds this argument unpersuasive, because of the reasons detailed above for the claims of Group I. Thus, LIEBSCHUTZ does not have to make up this deficiency in the primary references and the rejection should be maintained.

Group VIII:

Appellant argues that Claim 37 are not obvious over BOCKOW in view of EDWARDS because 1) there is no apparent reason to combine teachings of BOCKOW and EDWARDS as asserted by the Examiner based on the background knowledge in the art; and 2) one of skill in the art could not have predicted success in practicing the claimed invention by combining the elements of the prior art references in the manner that they would perform the same function as they did separately, as detailed above for the claims of Group VII. The Examiner finds this argument unpersuasive, because of the reasons detailed above for the claims of Group VII.

Appellant argues that LIEBSCHUTZ teaches a topical patch containing diclofenac epolamine in the preferred amount of 1% to 5%, but fails to teach the narrower range of about 0.5 to 2%. The Examiner finds this argument unpersuasive, because the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize.

Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as the least amount of pain killers to treat pain. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Appellant's invention.

Appellant argues that BOCKOW teaches away from a topical formulation containing 0.5 to 2% of NSAID because all it teaches is topical formulations containing 3-25% of NSAID. The Examiner finds this argument unpersuasive, because BOCKOW explicitly disclosed "the following examples are provided for purposes of illustration, not limitation" (see col. 7, line 26-27). Thus, BOCKOW is not limiting the amount of NSAID to 3-25% and is not teaching away from a topical formulation containing 0.5 to 2% of NSAID.

Group IX:

Appellant argues that Claim 32 is drawn to the method according to Claim 31, where the patch comprises 1.3% w/w of the NSAID. As such, the claim of Group IX includes all the elements of Claim 31 of Group VII and the element of Group VIII, which is a topical NSAID formulation comprising about 0.5 to 2% w/w of an active NSAID. Therefore, Appellants submit that the claim of Group IX is not obvious over Bockow in view of Edwards and Liebschutz for the reasons detailed above for the claims of Group

VII and VIII, respectively. The Examiner finds this argument unpersuasive, because of the reasons detailed above for the claims of Group VII and VIII, respectively.

Appellant argues that the references do not specifically teach adding the ingredients in the amount of 1.3% as claimed by Appellant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as the least amount of NSAID for optimal pain relief. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Appellant's invention.

Group X:

Appellant argues that the claim of Group IX is not obvious over Bockow in view of Edwards and Liebschutz for the reasons detailed above for the claims of Groups VII, VIII and IX, respectively. The Examiner finds this argument unpersuasive, because of the reasons detailed above for the claims of Groups VII, VIII and IX, respectively.

Appellant argues that LIEBSCHUTZ fails to teach polyester felt backing. The Examiner find this argument unpersuasive, because LIEBSCHUTZ teaches a protective layer composed on polyester attached to the patch (see pg. 5, 5th paragraph), which

would read on a polyester backing layering. Additionally, Appellant's polyester felt backing is simply a commercial available product called "Neurodol Tissugel" (see [0038]). It would have been obvious for one of ordinary skilled in the art to purchase a commercially available patch with polyester felt backing, because it would have been easier than making from scratch.

Group XI:

Appellant argues that claim 40 further includes that the NSAID is the only active agent of the topical NSAID formulation. The Examiner finds this argument unpersuasive, because claim 40 recites "comprises", which is open-language and could include other ingredients. Additionally, it would have been obvious for one skilled in the art to use one active agent only, such as NSAID, from a combination of two or more active agents, in which all the active agents are used for the same purpose, such as treating pain. BOCKOW disclosed NSAID, such as diclofenac, treats pain (see col. 5, line 38-41).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Jake M. Vu/
Examiner, Art Unit 1618

Conferees:

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Bennett Celsa/
Supervisory Patent Examiner, Art Unit 3991
Bennett Celsa, QAS TC 1600